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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/366,458	08/03/1999	WILLIAM J. DREYER	CIT1150-1	3096

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GRAY CARY WARE & FREIDENRICH LLP
4365 EXECUTIVE DRIVE
SUITE 1600
SAN DIEGO, CA 921212189

EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/03/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/366,458	DREYER, WILLIAM J.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 50-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 50-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 15, 17
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In view of newly discovered references, the finality of the previous Office action is withdrawn and prosecution on the merits continues.

Claims 1-10 and 50-64 are pending in the application and examined on the merits.

2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Claim Rejections Withdrawn:

4. The rejection of claims 1-10, and 50-57 under 35 U.S.C. 103(a) as being unpatentable over Nef and Nef, PNAS, Vol. 94, pages 4766-4771, April 1997, or Drutel et al., Receptors and Channels, Vol. 3, pages 33-40, 1995, or Vanderhaeghen et al., Biochemical and Biophysical Research Communications, Vol. 237, pages 283-287, 1997, or Mombaerts et al., Cell, Vol. 87, pages 675-686, November 15, 1996, in view of Janeway and Travers, Immunobiology, pages 2:20-2:30, 1997, or Stites et al., Basic and Clinical Immunology pages 291-293, 1987, or Schlossman et al., Purification of B Lymphocytes, pages 313-315, 1973, or Seed et al., PNAS, Vol. 84, pages 3365-3369, May 1987, or Wysocki et al., PNAS, Vol. 75, No. 6, pages 2844-2848, June 1978, or Aruffo et al., PNAS, Vol. 84, pages 8573-8577 , December, 1987, or Heller et al., PNAS USA, Vol. 94, pages 2150-2155, March 1997, or Foote, US Patent 5,661,628, August 26, 1997 is withdrawn in view of applicant's remarks.

New Grounds of Rejection:

5. Claims 10 and 57 are objected to because of the use of term "multiplexed", which is a term that is associated with nucleic acid detection techniques and not with protein detection techniques. It appears from the wording of the claims that applicant intends to claim methods where more than one probe is used for the purpose of detecting more than one protein. This objection may be overcome by amending the claims to clearly recite that more than one binding agent will be used in the claimed methods.

6. Claims 1-10 and 50-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the specification fails to describe a representative number of binding agents that are specific for serpentine cell surface receptors that are indicative of specific progenitor cell types or lineages; and fails to describe a representative number of binding agents that are specific for serpentine cell surface receptors that are indicative of specific cell types.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is for purposes of the 'written description' inquiry, "*whatever is now claimed*" (see page 1117). The specification does not "clearly allow persons

of ordinary skill in the art to recognize that [he or she] invented what is now claimed." (See Vas-Cath at page 1116.)

The claimed methods are drawn to methods of obtaining a composition substantially enriched in a specific progenitor cell type or substantially enriched in a specific cell type. The claimed methods comprise the use of "binding agents" that are specific for serpentine cell surface receptors, where the serpentine cell surface receptors are indicative of a specific progenitor cell type or lineage, or of a specific cell type. Examples of binding agents are antibodies or ligands that bind to serpentine cell surface receptors, where the serpentine cell surface receptors are indicative of a specific progenitor cell type or lineage, or of a specific cell type.

The skilled artisan cannot envision the detailed chemical structure of a representative number of molecules encompassed by the term "binding agents", because the specification fails to provide a description of a representative number of serpentine cell surface receptor proteins, where these specific serpentine cell surface receptor proteins are associated with specific progenitor cell types or lineages or with specific cell types. Without the structure of a serpentine cell surface receptor protein, the skilled artisan cannot make an antibody or use the receptor protein to discover a ligand. What the specification does provide is methods for discovering specific serpentine cell surface receptors that might be markers of progenitor cells or specific cell types, and the specification also presents theories underlying why serpentine cell surface receptors might be candidates in a search for markers of specific progenitor cell types or lineages, or specific cell types. However, this is not an adequate description of a representative number of serpentine cell surface receptor proteins that are serpentine cell surface receptor

proteins indicative of specific progenitor cell types or lineages or with specific cell types, because the specification fails to teach an association between the expression of any serpentine cell surface receptor protein and the existence of specific progenitor cell types or lineages, or specific cell types. Therefore, the specification fails to provide an adequate description of the structures of a representative number of serpentine cell surface receptor proteins, where these proteins are indicative of specific progenitor cell types or lineages or with specific cell types.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making or testing it. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. If applicant is not in possession of the genus of binding agents to be used in the claimed methods, then applicant is not in possession of the claimed methods of obtaining a composition substantially enriched in a specific progenitor cell type or of obtaining a compositions substantially enriched in a specific cell type, because possession of the binding agents is necessary for the operation of the claimed methods. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112, is severable from its enablement provision. (See page 1115).

7. Claims 50 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanabe (Tanabe, S. et al., The Journal of Immunology, 159: 905-911, 1997).

Claims 50 and 52 are drawn to methods of obtaining a composition substantially enriched in a specific cell type comprising contacting a sample of cells with at least one binding agent

specific for a serpentine cell surface receptor (seven transmembrane receptor or g-protein coupled receptor) such that the binding agent binds specifically to a cell or cells expressing the receptor in the sample; separating the cell or cells bound by the binding agent from the sample, thereby obtaining a cell or cells expressing the receptor; and separating from the cell or cells expressing the receptor a cell or cells that express at least one additional marker, thereby obtaining a composition substantially enriched in a specific cell type. The binding agent may be a ligand or an antibody.

Tanabe teaches isolation of MIP-1α receptor expressing astrocytes using a migration assay and then assaying the migrated astrocytes for GFAP expression using an anti-GFAP antibody (see page 908, 1st column). Tanabe teaches that MIP-1α is a chemokine and that chemokine receptors belong to the family of seven-transmembrane-spanning molecules that couple to heterotrimeric G proteins (page 907, 2nd column). Thus, Tanabe teaches a method for isolating MIP-1α receptor expressing astrocytes that is a method that is the same as that claimed.

8. Claims 1-4 and 50-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Aiuti (Aiuti, A. et al., J. Experimental Medicine, 185(1): 111-120, 1997) as evidenced by Tanabe (supra).

Claims 1-4 are drawn to methods of obtaining a composition substantially enriched in a specific progenitor cell type comprising contacting a sample of cells with a least one binding agent specific for a serpentine cell surface receptor indicative of a specific progenitor cell type or lineage such that the binding agent binds specifically to a progenitor cell or progenitor cells expressing the receptor in the sample; and separating the cells or cell bound by the binding agent

from the sample, thereby obtaining a compositions substantially enriched in a specific progenitor cell type. The method may further comprise separating from the cell or cells bound by the binding agent a cell or cells expressing at least one additional marker, and the marker may be CD-34 and the binding agent may be either a ligand or an antibody.

Aiuti teaches a method of separating SDF-1 receptor expressing hematopoeitic progenitor cells using a transendothelial migration assay (page 114, 1st column). The isolated SDF-1 receptor expressing cells were then phenotypically analyzed for CD34 and CD45 expression (page 112-113, bridging paragraph). As evidenced by Tanabe, the SDF-1 receptor is a chemokine receptor (CXCR-4 or fusin; page 905, first paragraph of Tanabe). Therefore, Aiuti teaches methods that are the same as that claimed.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
November 9, 2004

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
11/15/2004